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EXAMINER

KREMER, MATTHEW J

| | |
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| ART UNIT | PAPER NUMBER |
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3736

DATE MAILED: 01/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/712,895

Applicant(s)

PORGES ET AL.

Examiner

Matthew J Kremer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-28 and 31 is/are rejected.
- 7) ☒ Claim(s) 29,30 and 32-34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No: _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 23-26, 28, and 31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-6, 11, and 16 of U.S. Patent No. 6,675,031 to Porges et al. (Porges). Although the conflicting claims are not identical, they are not patentably distinct.

In regard to claim 23 of the present application, claim 5 of Porges claims a "system comprising a sensor and a monitor for sensing at least one physiological characteristic of a patient, the sensor being connectable to a monitor that estimates a physiological characteristic from signals detected by the sensor, the sensor comprising: a detector for detecting the signals from the patient which are indicative of the physiological characteristic; a memory connected with the sensor, said memory being physically located on one of a sensor body, sensor cable, sensor connecting plug or a

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sensor adapter module, and said memory being configured to store data defining at least one sensor signal specification boundary for the detected signals, the sensor signal specification boundary being indicative of a quality of the signals and an accuracy of the physiological characteristic estimated from the signals by the monitor; and means for providing access to the memory to allow transmission of the data defining the at least one sensor boundary to the monitor, wherein the monitor determines to display or not display the estimate of the physiological characteristic based on the signals and their relationship relative to a plurality of sensor signal specification boundaries and to a plurality of monitor boundaries preprogrammed into the monitor” (claim 1 of Porges from which claim 5 of Porges depends) and “the signals derived from detected light each having an AC modulation component and a DC component, and the sensor signal specification boundary including limits on the AC and DC components” (claim 5 of Porges). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 5 of Porges claims a system, which is narrower in scope than claim 23 of the present application. Claim 5 of Porges meets all the limitations set out in claim 23 of the present application and it would be obvious that the system of claim 5 of Porges is actually the system of claim 23 of the present application.

In regard to claim 24 of the present application, claim 4 of Porges claims a “system comprising a sensor and a monitor for sensing at least one physiological characteristic of a patient, the sensor being connectable to a monitor that estimates a physiological characteristic from signals detected by the sensor, the sensor comprising: a detector for detecting the signals from the patient which are indicative of the physiological

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characteristic; a memory connected with the sensor, said memory being physically located on one of a sensor body, sensor cable, sensor connecting plug or a sensor adapter module, and said memory being configured to store data defining at least one sensor signal specification boundary for the detected signals, the sensor signal specification boundary being indicative of a quality of the signals and an accuracy of the physiological characteristic estimated from the signals by the monitor; and means for providing access to the memory to allow transmission of the data defining the at least one sensor boundary to the monitor, wherein the monitor determines to display or not display the estimate of the physiological characteristic based on the signals and their relationship relative to a plurality of sensor signal specification boundaries and to a plurality of monitor boundaries preprogrammed into the monitor" (claim 1 of Porges from which claim 4 of Porges depends) and "wherein the monitor computes calculated values, having AC and DC components, from the signals, wherein the sensor signal specification boundary constitutes limits on the AC and DC components of the calculated values, and wherein the AC and DC components are dependent on either a physiological status of the patient, sensor type, or sensor location" (claim 4 of Porges). Although the conflicting claims are not identical, they are not patentably distinct from each other because the limitation "wherein the sensor signal specification boundary includes limits for an AC modulation component and DC component of the signals" (claim 23 of the present application) is met by the narrower limitation "wherein the sensor signal specification boundary constitutes limits on the AC and DC components of

the calculated values" from the signals. (claim 24 of the present application and claim 4 of Porges).

In regard to claim 25 of the present application, claim 5 of Porges claims "wherein the signals detected from the patient include first and second sets of signals derived from detected light scattered from the patient, the light having first and second wavelengths, the signals derived from detected light each having an AC modulation component and a DC component, and the sensor signal specification boundary including limits on the AC and DC components". (claim 5 of Porges).

In regard to claim 26 of the present application, claim 6 of Porges claims "wherein the signals derived from detected light are indicative of an arterial oxygen saturation of the patient". (claim 6 of Porges).

In regard to claim 28 of the present application, claim 11 of Porges claims a "monitor for providing an indication of an accuracy of an estimated physiological condition of a patient, the monitor being connectable to a sensor that detects signals indicative of at least one physiological characteristic of the patient, the monitor comprising: ... one receiving circuit configured to receive the signals indicative of the at least one physiological characteristic from the sensor and data defining at least one sensor signal specification boundary for the detected signals from the sensor, the sensor signal specification boundary being indicative of a quality of the signals detected by the sensor and an accuracy of the physiological characteristic estimated from the detected signals; ... one processing circuit configured to estimate the physiological condition of the patient based on the received signals, compare the received signals

against the at least one sensor boundary, and generate the indication of the accuracy of the estimated physiological condition; and means for providing the indication of the accuracy of the estimated physiological condition to a user of the monitor, wherein said processing circuit determines to display or not display the estimate of the physiological characteristic based on the signals and their relationship relative to a plurality of sensor signal specification boundaries and to a plurality of monitor boundaries preprogrammed into the monitor” (claim 9 of Porges from which claim 10 of Porges depends) and “wherein the at least one sensor boundary is indicative of a transition between a signal regime considered normal for the sensor in its usual application and a signal regime considered to be abnormal” (claim 10 of Porges from which claim 11 of Porges depends) and “wherein the...processing circuit is further configured to determine whether the received signals are within the normal regime or the abnormal regime” (claim 11 of Porges). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 11 of Porges claims a monitor, which is narrower in scope than claim 28 of the present application. Claim 11 of Porges meets all the limitations set out in claim 28 of the present application and it would be obvious that the monitor of claim 11 of Porges is actually the monitor of claim 28 of the present application.

In regard to claim 31 of the present application, claim 16 of Porges claims a “system comprising a sensor and a monitor for sensing at least one physiological characteristic of a patient, the sensor being connectable to a monitor that estimates the physiological characteristic from signals detected by the sensor, the sensor comprising:

a detector for detecting the signals from the patient which are indicative of the physiological characteristic; a memory connected with the sensor, said memory being physically located on one of a sensor body, sensor cable, sensor connecting plug or a sensor adapter module, and said memory being configured to store data defining at least one sensor signal specification boundary for the detected signals, the sensor signal specification boundary being indicative of a transition between a signal regime considered normal for the sensor in its usual application, and a signal regime considered to be abnormal; and means for providing access to the memory to allow transmission of the data defining the at least one sensor boundary to the monitor, wherein the monitor determines to display or not display the estimate of the physiological characteristic based on the signals and their relationship relative to a plurality of sensor signal specification boundaries and to a plurality of monitor boundaries preprogrammed into the monitor” (claim 14 of Porges from which claim 16 of Porges depends) and “said boundary is characteristic of individual components used in making the sensor” (claim 16 of Porges). Although the conflicting claims are not identical, they are not patentably distinct from each other because the limitation “said boundary is characteristic of individual components used in making the sensor” (claim 31 of the present application and claim 16 of Porges) is a narrower limitation of the limitation “said sensor signal specification boundary is characteristic of a model of the sensor” (claim 31 of the present application) since characteristics of individual components used in making a sensor necessarily are characteristics of a model of the sensor.

3. Claim 27 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,675,031 to Porges et al. (Porges) in view of U.S. patent 5,632,272 to Diab et al. (Diab) and further in view of U.S. Patent 5,779,630 to Fein et al. (Fein). Claim 5 of Porges does not claim that the physiological characteristic is arterial oxygen saturation. Claim 5 of Porges does claim the use of a system comprising a sensor and monitor for sensing at least one physiological characteristic of a patient in which the signals includes light having first and second wavelengths and each signal has an AC modulation component and a DC component. Diab teaches that a system measuring arterial oxygen saturation is a physiological sensor and monitor that includes light signals of two wavelengths that have an AC and DC component. (Fig. 11 and column 2, line 66 to column 3, line 3, line 10 of Diab). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the sensor and monitor of Diab in the claimed invention of Porges since Porges claims the use of a system comprising a sensor and monitor for sensing at least one physiological characteristic of a patient in which the signals include light having first and second wavelengths and each signal has an AC modulation component and a DC component and Diab teaches one such sensor and monitor. Porges does not claim that the memory is a digital memory. Fein teaches that a digital memory is a suitable memory. (claim 15 of Fein). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made

to use the digital memory of Fein in the claimed invention of Porges since Porges claims the use of a memory and Fein teaches one such memory.

Allowable Subject Matter

4. Claims 29-30 and 32-34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. The following is a statement of reasons for the indication of allowable subject matter. In regard to claim 29, the prior art does not teach or suggest said normal regime is one in which the sensor is likely to be properly applied to the patient and said abnormal regime is one in which the sensor may have partially or entirely come off the patient that is combined or combinable with the other limitations of claim 29. In regard to claim 30, the prior art does not teach or suggest that the processing circuit is further configured to compute an indication of whether the sensor is likely to be applied to the patient or has partially or entirely come off the patient. In regard to claim 32, the prior art does not teach or suggest that the monitor is a pulse oximetry monitor having means to determine whether the signals are within said normal regime or said abnormal regime and means for informing a user of the system as to whether the signal is normal or abnormal that is combined or combinable with the other limitations of claim 32.

Response to Arguments

6. Applicant's arguments with respect to claims 23-28 and 31 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

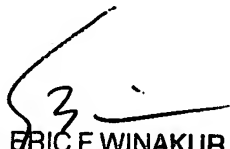
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 571-272-4727. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 3736



ERIC F. WINAKUR
PRIMARY EXAMINER